REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 2-7 were pending in this application when last examined and stand rejected.

Claims 2 and 6 are amended to clarify that the soluble outer membrane protein is the soluble F3 protein. Support can be found in the disclosure, for example, at page 7, lines 25-27 and in Example 1 on pages 13-14.

A comma was added in line 2 of claim 2 after "administration" to recite proper punctuation and grammar.

Claims 2, 3 6 and 7 are amended to italicize the genus and species names of the recited microorganisms.

Claims 2 and 6 are amended to correct a typographical error.

Dependent claims 3 and 4 are amended to recite "The composition" instead of "A composition" to use proper antecedent basis. Commas were inserted in these claims, after the recitation "according to claim 2" to use proper punctuation and grammar.

No new matter has been added.

II. INFORMATION DISCLOSURE STATEMENT

In item 2 on page 2 of the Office Action, it is indicated that the Office did not consider reference JP 60-72827 (designated AL) in the IDS of March 2, 2007 on the basis the submitted Abstract is for EP 0135073 and not for said Japanese patent.

It is respectfully submitted that JP 60-72827 should have been considered, because the submitted English Abstract for EP 0135073 is based on the European counterpart application of JP 60-72827. Pursuant to M.P.E.P. § 609.04(a)III, it is sufficient for Applicants to submit an English Abstract for corresponding related applications as a brief summary of the Japanese application. See attached M.P.E.P. pages 600-153 to 600-154.

Therefore, please consider JP 60-72827 and return an Examiner-initialed PTO-1449 form indicating such.

III. WRITTEN DESCRIPTION REJECTION

In item 4 on pages 3-8 of the Action, claims 2-7 were again rejected under 35 U.S.C. § 112, first paragraph, as lacking written description support for the claimed invention.

On page 4 of the Action, it was indicated that the claims are not drawn to a specific antibody defined by binding specificity. The Office argues that the Specification does not fully characterize the antigen used to immunize. The Office notes the claims encompass a vast genus of antigenic outer membrane proteins and immunogenic fragments thereof.

This rejection is respectfully traversed as applied to the amended claims.

The test for sufficiency of written description is whether the disclosure of the application reasonably conveys to the artisan that the inventor had possession at the time of filing of the subject matter which is claimed. See M.P.E.P. § 2163, I, 2100-159, 1st column, 2nd paragraph.

This test may be satisfied by: (1) a reduction to practice; (2) a reduction to drawings/chemical formulas; (3) a disclosure of relevant identifying characteristics, such as structure or other physical and/or chemical properties, to sufficiently describe the claimed invention in full, clear, concise and exact terms; (4) a disclosure of functional characteristics coupled with a known or disclosed correlation between function and structure; (5) a sufficient description of a representative number of species; or (6) a combination of the above, sufficient to show Applicants were in possession of the invention. See M.P.E.P. § 2163, 2100-170 to 2100-174, II, A, 3 a(i)-(ii).

In the instant case, claims 2 and 6 have been amended to further specify the antigen used to immunize. Specifically, the amended claims recite "soluble outer membrane protein of 18 to 27 kD from the merozoite of Eimeria acervulinau, wherein the soluble membrane protein is the soluble protein F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina*, *Eimeria tenella* and *Eimeria maxima*." Support for the soluble outer

membrane protein is the soluble F3 protein can be found in the disclosure, for example, at page 7, lines 25-27. See also Example 1 on pages 13-14.

The F3 protein necessarily has a common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina*, *Eimeria tenella* and *Eimeria maxima* in nature. The Applicants have found that infection with the three *Eimeria* species can be effectively prevented and treated by orally administering an antibody obtained from an egg of a chicken immunized with the specific antigen, *i.e.*, a soluble outer membrane protein of 18 to 27 kD (F3) from the merozoite of *Eimeria acervulina.*

Further, please note the F3 protein was well known in the art field prior to Applicants' priority date. Please see page 7, lines 25-27 and Example 1 on pages 13-14 of the disclosure. The Lillehoj et al. article (Avian Diseases, Vol. 44, pp. 379-389, April 2000), which is referenced in the disclosure at these locations, describes how to prepare the F3 protein. This reference was submitted to the Office in the IDS of March 6, 2006. A courtesy copy is attached herewith. Please see the description in the section, "Preparation of rabbit antisera" in the paragraph bridging pages 380 and 381. This reference clearly describes that an 18- to 29- kD fraction of *Eimeria acervulina* merozoite soluble antigen (F3) was obtained by preparative SDS-PAGE. The reference further describes rabbit antiserum against an 18- to 27-kD native protein fraction (F3) from *Eimeria acervulina* merozoites. See the Abstract on page 379.

Thus, the protein used to immunize to obtain the antibody in the present invention was known and fully characterized in the art. Also, it is respectfully submitted that the skilled artisan could obtain the protein F3 based on the instant disclosure and the knowledge in the art.

In this regard, it is well established that the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. See M.P.E.P. § 2164.05(a).

Accordingly, in reply to the Office's position on page 4 of the Action that the specification does not fully characterize the antigen used to immunize, it is respectfully submitted that Applicants need not do so since the F3 protein was well known and characterized in the art.

Nonetheless, please also see Example 1 on pages 13-14, which describes an experiment to obtain the soluble outer membrane protein of 18 to 27 kD. This Example further describes production of the claimed antibody. Please note that F3 is not an isolated protein, but rather an 18- to 27-kD protein fraction. Thus, Applicants have demonstrated possession by an actual reduction to practice of the present invention for both the claimed antibody and the antigen used to immunize to obtain the antibody.

As is understood from Example 1 of the present disclosure, the F3 protein is used for immunizing a chicken. Therefore, any information about epitope regions thereof is not important and is not required for carrying out the present invention.

Further, in reply, to the Office's assertion (on page 6 of the Action) that the claims "are drawn to a vast genus of antigenic outer membrane proteins and immunogenic fragments thereof", please note the "immunogenic fragments" language was deleted from claims 2 and 6 in the response filed December 22, 2006.

Accordingly, it is respectfully submitted that the claims do not encompass a vast number of antigenic outer membrane proteins. Again, the amended claims are directed to the soluble outer membrane protein of 18 to 27 kD from the merozoite of *Eimeria acervulinau*, wherein the soluble membrane protein is the soluble protein F3, which has common immunogenicity shared among sporozoite and merozoite of *Eimeria acervulina*, *Eimeria tenella* and *Eimeria maxima* which are associated with chicken coccidiosis, and a lactic acid bacterium.

Based on the above, it is respectfully submitted that the specification provides adequate written description support to show that Applicants were in possession of the claimed invention at the time of filing.

For these reasons, the 112, first paragraph, written description rejection of claims 2-7 is untenable and should be withdrawn.

IV. CLAIM OBJECTION

In item 5 on page 9 of the Action, claims 2, 3, 6 and 7 were objected to for minor informalities.

The present amendment overcomes this objection.

Specifically, claims 2, 3 6 and 7 have been amended to italicize the genus and species names of the recited microorganisms as suggested by the Examiner. Claim 2 has also been amended to correct a typographical error as suggested by the Examiner.

V. ENABLEMENT REJECTION

In item 6 on page 9-15 of the Action, claims 2-7 were newly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. This is a new ground of rejection.

The Office takes the position that the specification is not enabled for any aspect of the claimed invention. In this regard, the Office argues that it is unclear how the skilled artisan would obtain the antibody to meet the recitation of treating or preventing chicken coccidiosis.

This rejection is respectfully traversed as applied to the amended claims for the reasons set forth above in the reply to the written description rejection and for the following reasons.

The Office did not find persuasive the Rule 132 Declaration submitted on December 22, 2006 with the last response. The Office argued that the Kodama Declaration is deficient, because it lacks a negative control against *Eimeria* species.

Applicants respectfully disagree and submit that the preventative effect of the antibody of the present invention was demonstrated in the previous Declaration for the reasons of record.

Nonetheless, attached herewith is a further Rule 132 Declaration by Dr. Kodama (the Applicant). This Declaration further demonstrates that the claimed composition is capable of inducing protective immunity against chicken coccidiosis.

In item 2 on page 1 of the Declaration, it described that the anti-chicken coccidiosis antibody produced in Example 1 of the present invention was administered in feed to chickens. After administration, the chickens were infected with oocysts of *Eimeria tenella*. As a control, the chickens which had been administered the standard broiler feed without the antibody and were not infected were also observed.

On page 2, the Declaration demonstrates that administration of the claimed antibody before infection resulted in ***significantly improved*** conditions of the chickens after infection, including improvements in weight gain and feed conversion ratio. Accordingly, the Declaration proves the claimed antibody to be very effective in preventing chicken coccidiosis. See the results in Table 1 on page 2 of the Declaration.

Thus, this Declaration and the previous Declarations provide sufficient experimental evidence demonstrating the effectiveness of the claimed composition in inducing protective immunity against chicken coccidiosis.

In view of the forgoing, favorable reconsideration and withdrawal of this ground of rejection is deemed appropriate.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Yoshikatsu KODAMA et al.

By: _____
Jay F. Williams
Registration No. 48,036
Attorney for Applicants

JFW/mjw
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
June 8, 2007

ATTACHMENTS

1. Rule 132 Declaration by Dr. Kodama;
2. Lillehoj et al., Avian Diseases, Vol. 44, pp. 379-389, April 2000; and
3. Copies of M.P.E.P. § 609.04(a)III, pages 600-153 to 600-154.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of
Yoshikatsu KODAMA et al.
Serial No. 10/519,536
Filed: December 28, 2004
For: ANTI-CHICKEN COCCIDIOSIS COMPOSITION

Atty. Docket No.: 2004_2037A
Art Unit: 1645
Examiner: TONGUE, LAKIA J

DECLARATION PURSUANT TO 37 C.F.R.1.132

1. I, Yoshikatsu KODAMA, do hereby declare as follows:

I had Ph.D. from University of Tokyo in 1978. Since April, 1978, I have been employed by GHEN Corporation. I have a full knowledge of the present invention and cited references.

2. In order to demonstrate that the antibody of the present invention is capable of inducing protective immunity against chicken coccidiosis.

The anti-chicken coccidiosis antibody produced in Example 1 of the present application (United States Patent Application Serial No. 10/519,536) is added to a standard broiler feed. The animal used in this evaluation was 10 day old "Chunky" which is a strain specifically developed for broiler production and had not been infected with chicken coccidiosis. The antibody was administered to the chickens by adding the antibody to the standard broiler feed at a concentration of 0.1 %, 1 %, and 10 %. After 3 day administration of the feed comprising the antibody, the chickens were infected with oocysts of Eimeria tenella (ET strain) at 5000 oocysts/animal (J. Protozool, 9: 154-161, 1962). As a negative control, the chickens which had been administered the standard broiler feed without the antibody were also infected with oocysts of Eimeria tenella (ET strain) at 5000 oocysts/animal. As a control, the chickens which had been administered the standard broiler feed without the antibody and were not infected were also observed. Each group includes 10 chickens.

The chickens were observed for 2 weeks after the infection. The chickens were continuously administered the standard broiler feed with or without the antibody for said 2 weeks.

The chickens were mainly observed for their weight gain and feed conversion rate. O.P.G. (oocysts per gram of faeces) was also observed. Significant effects in the weight gain were confirmed in the group that had been given the feed comprising 10 % of the antibody. Also, significant effects in the feed conversion ratio were confirmed in all the groups that had been given the feed comprising the antibody.

As evidence from the results, by administration of the feed comprising the antibody to the chickens before infection, the conditions of the chickens including the weight gain and the feed conversion ratio are significantly improved after the infection. The overall effect of the test substance was determined by using the scores of each observation, and the antibody was proved to be very effective in preventing chicken coccidiosis.

Table 1

	Uninfected	Infected with *E. tenella*			
	Control*	Negative control**	Proportion of the antibody added to the feed		
	0%	0%	0.1%	1%	10%
Average weight gain (g)	600	578	590	574	662
Relative weight gain (%)[a]	100	96	98	96	110
Average feed intake (g)	859	885	850	849	895
Feed conversion rate[b]	1.43	1.53	1.44	1.48	1.35
Suvival rate(%)	100	100	100	90	100
OPG (x 10^4) at 7th day	0.0	5.5	4.6	9.7	12.0

*) Group which had been administered the standard broiler feed without the antibody and was not infected.

**) Group which had been administered the standard broiler feed without the antibody and was infected.

a) Relative weight gain (%) = [weight gain of the infected group] / [weight gain of the uninfected group] x 100

b) Feed conversion ratio = [average feed intake] / [average weight gain]

3. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: This 31th day of May, 2007

Yoshikatsu KODAMA